



Patent

Attorney Docket No. 01662/58602

JFE

**U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE****INFORMATION DISCLOSURE
STATEMENT**Docket Number:
01662/58602Application Number
10/511,987Filing Date
October 21, 2004Examiner
Lao MarialouisaArt Unit
1621Invention Title
**Pharmaceutical Composition Containing Lamotrigine
Particles of Defined Morphology**Inventors
ARONHIME, et al.

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with
the United States Postal Service with sufficient postage as first
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Mail Stop: Amendment, Commissioner for Patents, P.O. Box
1450, Alexandria, VA 22313-1450 on

Date: **4-9-07**Signature: *Jennifer C. Buscemi*

Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to **Kenyon & Kenyon LLP, deposit account 11-0600**.

☐ 1. This Information Disclosure Statement is being filed (a) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d), (b) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, (c) before the mailing date of a first Office Action on the merits in the present application, OR (d) before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

☒ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a final action, Notice of Allowance, or any action that otherwise closes prosecution.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR § 1.97(e)(1).

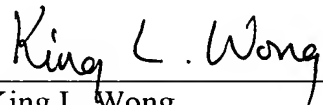
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☒ c. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 CFR §1.97(c)(2).
- ☐ 3. This Information Disclosure Statement is being filed after the mailing date of a final action, Notice of Allowance or an action that otherwise closes prosecution, but before payment of the Issue Fee. Applicant(s) hereby request(s) that the Information Disclosure Statement be considered. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the petition fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in any counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☐ 4. Relevance of the non-English language reference(s) is discussed in the present specification.
- ☐ 5. The references were cited in office actions in counterpart foreign applications. English language version of the foreign corresponding foreign office actions and responses thereto are attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language reference(s) appears in the Appendix attached hereto.
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination of the present application.
- ☐ 8. This application is one of a series of related applications, identified in the attached Appendix, which are directed to related technical subject matter. The identification of those U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is

respectfully requested to consider the cited applications and the art cited therein during the examination.

- ☐ 9. The reference(s) was/were cited by or submitted to the Office in parent application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).
- ☐ 10. English-language Abstracts of the non-English language references are attached hereto.
- ☒ 11. Since this application was filed after June 30, 2003, copies of U.S. references are not included.
- ☒ 12. Other. Some of the references cited herein were cited in an International Search Report of PCT/US2003/13002 provided herewith.

Respectfully submitted,

Date: March 26, 2007



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	10/511,987
Filing Date	October 21, 2004
First Named Inventor	Judith Aronhime
Art Unit	1621
Examiner Name	Lao Marialouisa
Attorney Docket Number	1662/58602

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BRITTAİN, H.G., Polymorphisim in Pharmaceutical Solids pp. 66, 128-129, 183, 185-186, 203, 205-209, 228-229, 235-236, Marcel Dekker 1999.	
		BRUNAUER, S. , P.H. Emmett, E. Teller, J. Am. Chem. Soc., 1938, 60, 309-319.	
		E. SCHMITT et al "Moisture-Dependent Crystallization of Amorphous Lamotrigine Mesylate" Journal of Pharmaceutical Sciences, Vol. 85, No. 11, November 1996, pgs 1215-1219.	
		JANES et al., "Structure of Lamotrigine Methanol Solvate: 3,5-Diamino-6-(2,3-dichlorophenyl)-1,2,4-triazine-Methanol, a Novel Anticonvulsant Drug," Acta Crystallographica, 1989, C45, 129-132.	
		Perry's Chemical Engineers" Handbook, 6 th ed. p. 15-21 (1984).	
		Pharmacopeial Forum, Vol. 24, No. 1, (Jan-Feb. 1998) p. 5438-5440.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.